

05/19/04

JFW

<b>TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT</b> (Under 37 CFR 1.97(b) or 1.97(c))		Docket No. 047221-00003	
In Patent Application Of: Harvey et al.			
Serial No. 10/787,350	Filing Date 2/26/2004	Examiner TBD	Group Art Unit TBD
Title: DIETARY SUPPLEMENT			
Address to: Assistant Commissioner for Patents Washington, D.C. 20231			
<b>37 CFR 1.97(b)</b>			
1. <input checked="" type="checkbox"/> The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.			
<b>37 CFR 1.97(c)</b>			
2. <input type="checkbox"/> The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:			
<input type="checkbox"/> the statement specified in 37 CFR 1.97(e);			
OR			
<input type="checkbox"/> the fee set forth in 37 CFR 1.17(p).			

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
047221-00003

In: Re Application: Harvey et al.

Serial No.

10/787,350

Filing Date

2/26/2004

Examiner

TBD

Group Art Unit

TBD

**DIETARY SUPPLEMENT**

**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Assistant Commissioner is hereby authorized to charge and credit Deposit Account No. 501346 as described below. A duplicate copy of this sheet is enclosed.
- ☐ Charge the amount of \_\_\_\_\_
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\*This certificate may only be used if paying by deposit account.

  
Signature

Dated: 5/17/04

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CC:



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of

Bryce M. Harvey, et al.

For: DIETARY SUPPLEMENT

U.S. Serial No. 10/787,350

Filed: February 26, 2004

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P.O. Box 55727  
Birmingham, Alabama 35255-5727  
May 18, 2004

Commissioner for Patents  
Mail Stop DD  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Applicant hereby submits an Information Disclosure Statement in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98, for the above-identified application and Form PTO-1449 listing seven (7) United States patents nine (9) patent application publications and sixteen (16) articles. Copies of the patents, patent application publications and articles are also enclosed.

Applicant further submits that none of the enclosed patents or patent application publications render the claims of the application unpatentable; however, the patents are provided for the Examiner's consideration.

In particular, the current invention differs from all of the disclosed references in that none of the retrieved references disclose the identical combination of elements encompassed within the invention.

Applicant makes no representation that a search has been made or, if made, was complete, or that no more pertinent art than that listed is available. It is expected that the Patent and Trademark Office will conduct an independent search for relevant references.

Respectfully submitted,

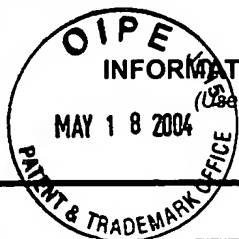
SIROTE & PERMUTT, P.C.

By:

A handwritten signature in black ink, appearing to read 'C. Browning', with a stylized flourish at the end.

C. Brandon Browning  
Reg. No. 44,570  
205-930-5141

CBB:tr  
Enclosures

**INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)

ATTY DOCKET NO.  
047221-00003SERIAL NO.  
10/787,350FILING  
2/26/2004

GROUP

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A	5,405,613	4/11/1995	Rowland			
	B	5,543,146	8/6/1996	Perez			
	C	5,807,586	9/15/1998	Jackson et al.			
	D	5,976,568	11/2/1999	Riley			
	E	6,197,309 B1	3/6/2001	Wheeler			
	F	US/2002/0001632 A1	1/3/2002	Revel			
	G	US/2002/0001633 A1	1/3/2002	Revel			
	H	6,399,115 B2	6/4/2002	Revel			
	I	US/2002/0132800 A1	9/19/2002	Popp et al.			
	J	US/2002/0137797 A1	9/26/2002	Meyskens, Jr. et al.			
	K	US/2002/0155163 A1	10/24/2002	Benjamin et al.			

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	L	Kucuk, Omer et al., Effects of Lycopene Supplementation in Patients with Localized Prostate Cancer; Society for Experimental Biology and Medicine, 2002
	M	Weinstein, Stephanie J., et al., Null Association between Prostate Cancer and Serum Folate, Vitamin B6, Vitamin B12 and Homocysteine; November 2003, Vol. 12, pp. 1271-1272

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE CITATION</b> <i>(Use several sheets if necessary)</i>				ATTY DOCKET NO. <b>047221-00003</b>		SERIAL NO. <b>10/787,350</b>	
				FILING <b>2/26/2004</b>		GROUP	
<b>U.S. PATENT DOCUMENTS</b>							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
N		US/2003/0018066 A1	1/23/2003	Fleshner			
O		6,555,142 B1	4/29/2003	Green			
P		US/2003/0096009 A1	5/22/2003	Randhava et al.			
Q		US/2003/0096024 A1	5/22/2003	Randhava et al.			
R		US/2003/0147995 A1	8/7/2003	Koss et al.			
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES      NO
<b>OTHER DOCUMENTS    (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	S	Klein, Eric A., et al., The Selenium and Vitamin E Cancer Prevention Trial, March 2003					
	T	Wilt T, Ishani et al., Serenoa repens for benign prostatic hyperplasia (Cochrane Review) Issue 3, 2002					
EXAMINER				DATE CONSIDERED			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

<b>INFORMATION DISCLOSURE CITATION</b> <i>(Use several sheets if necessary)</i>		Docket Number (Optional) <b>047221-00003</b>	Application Number <b>10/787,350</b>
		Applicant(s) <b>Harvey et al.</b>	
		Filing Date <b>2/26/2004</b>	Group Art Unit

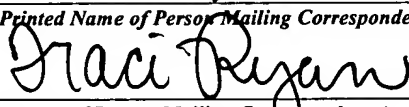
  

*EXAMINER INITIAL	OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>
U	Chen, Longwen, et al., Oxidative DNA Damages in Prostate Cancer Patients Consuming Tomato Sauce-Based Entrees as a Whole-Food Intervention, Journal of the National Cancer Institute, December 2001
V	Wilt, Timothy J., et al. Saw Palmetto Extracts for Treatment of Bening Prostatic Hyperplasia, November 1998
W	Veltri, Robert M., et al., Saw Palmetto Alters Nuclear Measurements Reflecting DNA Content in Men with Symptomatic BPH: Evidence for a Possible Molecular Mechanism, Urology 60, 2002
X	Richards, La'Toya Ross et al. The Synergistic Effect of Conventional and Sustained Delivery of Antioxidants on LNCaP Prostate Cancer Cell Line
Y	Venkateswaran, Vasundara et al., Modulation of Cell Proliferation and Cell Cycle Regulators by Vitamin E in Human Prostate Carcinoma Cell Lines, The Journal of Urology 2002
Z	Lasalvia-Prisco, Eduardo et al., Serum Markers Variation Consistent with Autoshizis Induced By Ascorbic Acid-Menadione in Patients with Prostate Cancer, Medical Oncology 2003
AA	Helzlsouer, Kathy J., Association Between ( )Tocopherol, ( )Tocopherol, Selenium and Subsequent Prostate Cancer, Journal of the National Cancer Institute 2000
BB	Heijmans, Bastiaan T. et al., A Common Variant of the Methylenetetrahydrofolate Reductase Gene (1p36) Is Associated with an Increased Risk of Cancer, Cancer Research, 2003
CC	Moyad, Mark A., et al., Vitamin E, Alpha - and Gamma-Tocopherol and Prostate Cancer, Seminars in Urologic Oncology, 1999, pp. 85-90
DD	Ni J, Chen, et al. Vitamin E succinate inhibits human prostate cancer cell growth via modulating cell cycle regulatory machinery, National Library of Medicine 2004
EE	Zu K, Ip C., Synergy between selenium and vitamin E in apoptosis induction is associated with activation of distinctive initiator caspases in human prostate cancer cells, National Library of Medicine 2004
FF	Selhub, J., et al., Vitamin status and intake as primary determinants of homocysteine in an elderly population, American Medical Association, 1993

EXAMINER	DATE CONSIDERED
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\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)</b> Applicant(s): Bryce M. Harvey et al.			Docket No. 47721-00003	
Serial No. 10/787,350	Filing Date 2/26/2004	Examiner TBD	Group Art Unit TBD	
Invention: <b>DIETARY SUPPLEMENT</b>				
I hereby certify that the following correspondence: <div style="border: 1px solid black; padding: 10px; margin: 10px 0;">Information Disclosure Statement with attached patents, patent publications and articles and postal receipt card</div> <p style="text-align: center;"><i>(Identify type of correspondence)</i></p> is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on <div style="text-align: center; margin: 10px 0;"><u>5/18/2004</u> <i>(Date)</i></div> <div style="text-align: center; margin: 10px 0;"><u>Traci Ryan</u> <i>(Typed or Printed Name of Person Mailing Correspondence)</i>  <i>(Signature of Person Mailing Correspondence)</i></div> <div style="text-align: center; margin: 10px 0;"><u>ET 807673944 US</u> <i>("Express Mail" Mailing Label Number)</i></div>				
Note: Each paper must have its own certificate of mailing.				